



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,635	05/14/2001	Bengt Krister Olson	59486.000002	7285

7590 05/05/2004
Stanislaus Aksman
Hunton & Williams
Suite 1200
1900 K Street, N.W.
Washington, DC 20006

EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,635	OLSON, BENGT KRISTER	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-69, 71-76 and 78-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-69, 71-76 and 78-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Request for continued examination (i.e., RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on February 17, 2004 after a Final action was mailed on June 16, 2003 and a subsequent Advisory action was mailed on December 11, 2003. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action mailed 06/16/2003 has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2004 has been entered. Accordingly an RCE has been established and the action on RCE follows.

CLAIMS STATUS

2. Applicants' Responsive amendment filed 02/17/2004 is acknowledged and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 89-91 have been added.
4. Claims 1-64, 70, 72 and 77 have been cancelled.
5. Claims 65, 68-71, 73-75 and 78-84 have been amended.
6. Claims 65-69, 71, 73-76 and 78-91 are pending and are examined on Merits

Claims Objection

7. Claims 65, 68 and 75 are objected for the reasons noted below:
 - Claim 65 lacks the intended use (e.g., for oral administration) of the claimed composition.
 - In Claim 75, "xanthofyll" is misspelled. Appropriate correction (i.e., xanthophyll) is required.

Claim Rejections Under 35 U.S.C. § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 65-69, 71, 73-76 and 78-91 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for preparing a "grape seed extract", does not reasonably provide enablement for preparing a "cartilage extract", "fish extract", "plant extract" or "tomato Extract". The

specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

From the record of the present written disclosure, applicants have demonstrated a composition comprising grape seed extract, wherein steps to prepare grape seed extract are also described (Specification, Page 8, Lines 24-31) and a Cartilage enzymatic hydrolysate (Specification, Page 5, Lines 10-15. Applicants have, however, not provided any clear guidance regarding the preparation of "cartilage extract", "fish extract", "plant extract" or "tomato Extract". Furthermore, even the preparation of cartilage enzymatic hydrolysate does not clearly define all the steps (e.g., enzyme dosage, enzyme to substrate ratio, duration of reaction, temperature, pressure, any co-catalyst used etc.)

An artisan in the art would not be able to practice the invention because an undue experimentation without reasonable expectation of success will be required to prepare "cartilage hydrolysate", "cartilage extract", "fish extract", "plant extract" or "tomato Extract", other than the "grape seed extract" according to the recitation in instantly claimed invention. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

10. Claims 65-69, 71, 73-76 and 78-91 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- As currently presented, Claims 65-69, 71, 73-76 and 78-91 are very confusing and unclear. For e.g., from their presentation in current form, Claims 65, 68, 71, 73, 74, 76, 78 and 80-90 do not clarify:
 - Whether applicant's claimed composition is comprised of chemicals/ingredients obtained from natural or synthetic sources or what is the real source for the components comprising applicant's claimed composition?,
 - Whether the composition is comprised of cartilage extract/fish extract, grape seed extract, plant extract, tomato extract or of the components/chemical compounds that may be present in extracts obtained from those sources in a particular method, wherein each and every step, including a recovery step for a particular chemical compound/component is clearly delineated,
 - Applicant needs to clearly state the claimed composition in an independent claim/claims and in subsequent/ dependent claims indicate same component/chemical compound. E.g., if lycopene, rather than tomato extract is the lipophilic antioxidant component comprising applicant's claimed composition, applicant should state lycopene in

subsequent/dependent claims rather interchangeably using lycopene and tomato extract. This is because tomato extract, depending on the steps of preparing said extract and solvents utilized to prepare said extract would have a composition entirely different than that of a composition comprising lycopene alone. Same criteria applies for cartilage extract, grape seed extract, plant extract, fish extract and any other extract that the applicant is claiming as a component for the claimed composition.

- Examiner suggests that applicant should rewrite Claims 65, 68, 71, 73, 74, 76, 78 and 80-90 along the Examiner's suggestion stated *supra*. In rewriting, said Claims, however, applicant should ensure that no new matter is added.
- Claim 65 is incomplete in the absence of statement regarding the intended use of the Claimed composition. For example, "A pharmaceutical composition comprising".
- While there is no specific rule or statutory requirement which specifically addresses the need for an intended use of a composition, it is clear from the record and would be expected from conventional preparation processes that the product must have a use. Thus, Claim 65 fails to particularly point out and distinctly claim the "complete" composition. The metes and bounds of the claimed composition are therefore not clearly established or delineated.
- While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "extract" in claim 65 is used by the claim to describe a "cartilage hydrolysate", rather than an extract from the cartilage because said "cartilage extract" is obtained via "enzymatic cleavage of the cartilage". Examiner suggests that the applicant clarify whether a cartilage extract or a "cartilage enzymatic hydrolysate" is the component comprising claimed composition.
- Claim 65 is rendered vague and indefinite because of the terms, "obtainable" and "extractable". These terms, in and of itself do not define their metes and bounds. Furthermore, they are not defined in those claims, the specification does not provide a standard for ascertaining the requisite degree for "extractable" and "obtainable", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention because said term does not clearly define the claimed subject matter. Appropriate correction is required.
- Claims 65-66, 74, 80-81 and 83-89 are rendered vague and indefinite by the term "extract" in those Claims because in those Claims, this term, in and of itself, does not adequately delineate its metes and bounds. For example, is said extract obtained by extraction with water, a polar solvent, a non-polar solvent, an acid or base, a squeezed extract, or something else? Furthermore, in claims where tomato/ cartilage or fish extract is recited, the plant/ animal part

(e.g., tomato seed or fruit/ fish bone or cartilage) should also be clearly specified because for e.g., it is well accepted in the herbal art that extraction with one of various distinct solvents, as well as from particular parts of therapeutic plants/herbs, has a profound impact on the final product with respect to the presence, absence, amounts, and/or ratios of active ingredients therein. Since the extract/extracts themselves are clearly essential to the claimed invention, the steps(s) by which the claimed extract/ extracts are obtained are also clearly essential and, therefore, must be recited in the claim language itself. Accordingly, without the recitation of all these critical limitations as set forth above, the claims do not adequately define the instant invention.

- Examiner suggests as a guidance that Applicant should for e.g., define the terms: " cartilage extract", "fish Extract", "plant extract", "tomato extract" etc. with the same/similar verbiage as has been used to define the "grape seed extract" at Page 8, Lines 24-31 of the specification.
- Claims 71, 80-83, 86, 89 and 90 are rendered unclear and vague because in those claims the quantities and or ratios are recited in relation to an extract and a particular chemical compound.. E.g., in Claim 71 the ratio between lycopene and hydrophilic antioxidant is defined on weight to weight ratio between one or more hydrophilic antioxidants extracted from grape seeds, wherein "the ratio between the grape seed extract and lycopene is". In this example if the ratio between grape seed extract and lycopene is considered, the ratio of individual components within the grape seed extract to lycopene will be less in contrast to a composition, wherein ratio between a particular component of grape seed to lycopene will be taken into account to define the weight ratio of said composition. Thus, Claims 71, 80-83, 86, 89 and 90 recite the broad recitation, and the narrower statement of the range/limitation within the same claim.
- In Claims 86 and 87 are recited the limitations "fish extract", "plant extract", "*Acerola* extract, "microcrystalline cellulose", "silicone dioxide", "inulin", "ascorbic acid" and "gluconate". There is insufficient antecedent basis for this limitation in the cited claim, because Claim 65 from which Claims 86 and 87 depend does not cite "fish extract", "plant extract", "*Acerola* extract, "microcrystalline cellulose", "silicone dioxide", "inulin", "ascorbic acid" and "gluconate".
- Claim 88 is rendered vague and indefinite because of the phrases "slow release" and "normal release" at Line 2. These terms are subjective and therefore, do not establish any metes and bounds to distinguish one term from another. An artisan skilled in the art will not be able to distinguish among the terms as discussed above. It is also not clear how the same composition would simultaneously have both "slow release" and "normal release" components? Applicants are

requested to define or clarify the phrases "slow release" and "normal release". Furthermore, if lycopene is a plant extract (i.e., obtained from tomato and tomato is a plant), how can same extract have "slow release" and "normal release" properties, unless there are very specific conditions to prepare a "plant extract" and a "tomato extract"?

- The phrase, " form suitable for oral administration" in claim 91 is unclear, vague, confusing and indefinite. It is not clear how one can determine with clarity and accuracy what form of a composition is suitable (i. e., capsule, concoction, elixir, powder, syrup or tablet), and what may be a suitable form for one may not be suitable for another. Applicant is advised to define the phrase " form suitable for oral administration".

All other claims depend directly or indirectly from the rejected claim (65) and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

Claim Rejections Under 35 U.S.C. § 102

11. Claims 65-69, 73-75 and 78 are rejected under 35 U.S.C. §102(b) as anticipated by Greenberg (U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402).

Claims recite a composition comprising cartilage extract or compounds extractable from cartilage, hydrophilic antioxidants and lycopene, wherein said antioxidants are obtained from a synthetic or natural source. The said antioxidants are comprised of plant extract components, more specifically oligomeric procyanidol, lycopene and carotenes.

Greenberg discloses a composition comprising chondroitin sulphate (i.e., mucopolysaccharides= glycosaminoglycan), extracts from *Ginkgo biloba* and *Silybum marianum*, proanthocyanidins, vitamin C, vitamin E and β -carotene (Column 2, Lines 63-67; Column 3, Lines 36-40). Thus, Greenberg discloses a composition comprising cartilage extract compound (e.g., chondroitin sulphate= mucopolysaccharides= glycosaminoglycan), lipophilic (e.g., vitamin E and β -carotene) and hydrophilic (e.g., proanthocyanidin from red wine grapes and extract of *Ginkgo biloba*) antioxidants. Since proanthocyanidin obtained from wine grapes is a component of the said composition, the said composition also comprises oligomeric procyanidol (See Bombardelli et al., Page 7, Lines 1-2).

Therefore, the reference is deemed to anticipate the cited claims.

Please note that Bombardelli et al., is cited to merely support the constituents of hydrophilic and lipophilic antioxidants and not as a prior art reference.

12 In response to art rejections to Claims 65- under 35 U.S.C. §102(b) as anticipated by Greenberg

(U.S. Patent 5,569,458) with evidence provided by Bombardelli et al (EP 0,659, 402) in Office Action mailed ----, applicant argues that Greenberg's exhaustive list of components comprising the composition that Greenberg teaches does not comprise either lycopene or chondroitin sulphate. Applicant's arguments have been fully considered but are not persuasive for the reasons of record on Page 5 under item 9 of said Office action. Since the examiner-cited reference teaches a composition comprising cartilage extract, hydrophilic antioxidants, lycopene and beta-carotene (see Column 2, Line 63) an antioxidant according to applicant's own assertion, Greenberg's composition teaches a composition comprising a cartilage extract, hydrophilic antioxidants, lycopene and beta carotene (See Column 3, Line 36 after the word "trypsin"). As discussed *supra*, Greenberg's composition inherently comprises both antioxidants because said composition is comprised of proanthocyanidins from Red wine grapes (See Column 3, Line 37) and beta carotene (i.e., β -carotene)

Claim Rejections Under 35 U.S.C. § 103(a)

13. Claims 65-85 and 88 are rejected under 35 U.S.C. § 103 (a) as obvious over Greenberg (U.S. Patent 5,569,458) in view of Spraycar, Bombardelli et al. (EP 0,655,402) and, Kosbab (WO 00/07607).

Claims recite a composition comprising cartilage extract or a compound (i.e., glycosaminoglycan) obtained from cartilage extract, hydrophilic antioxidants and lycopene, wherein said hydrophilic antioxidants are obtained from a synthetic or natural source. Said natural source are plant extract components, more specifically oligomeric procyanidol, lycopene and carotenes. The source for said plant extracts are anyone of following plants: *Aesculus hippocastanum*, *Ginkgo biloba*, pine bark, *Silybum marianum*, tomato, *Vaccinium myrtillus* and *Vitis vinifera*.

Greenberg teaches a composition comprising chondroitin sulphate, mucopolysaccharides, extracts from *Ginkgo biloba* and *Silybum marianum*, proanthocyanidins, vitamin E and β -carotene, zinc, ascorbic acid (Column 2, Lines 63-67; Column 3, Lines 36-40). Thus, Greenberg discloses a composition comprising cartilage extract compound (e.g., chondroitin sulphate), lipophilic (e.g., vitamin E and β -carotene) and hydrophilic (e.g., proanthocyanidin from red wine grapes and extract of *Ginkgo biloba*) antioxidants. Please note that chondroitin sulphate is a glycosaminoglycan (Applicant's Specification at Page 5, Lines 1-4). Furthermore, glycosaminoglycan is synonym with mucopolysaccharide (see Stedman's Medical Dictionary, Page 1134, Column 2, Lines 9-14)

Greenberg, however, does not teach in his composition grape seed extract and procyanidole oligomers, different plants as the natural source of antioxidants, different sources of lipophilic antioxidants (e.g., lycopene, xanthophylls, carotenes) and tomato extract as the source of lycopene. Furthermore, Greenberg does not identify hydrophilic antioxidant components of his composition.

Bombardelli et al., teach a composition comprising hydrophilic antioxidants with lycopene, wherein the sources for hydrophilic antioxidants are: silymarin, proanthocyanidin and procyanidole oligomers extracted from *Aesculus hippocastanum*, *Camelia sinensis*, *Ginkgo biloba* or *Vitis vinifera*. Said composition also comprises β -carotene, lycopene and vitamin E wherein tomato is the source of lycopene (Page 6, Lines 47-53 and Page 7, Lines 1-4). Thus, Bombardelli et al. clearly define the sources of hydrophilic antioxidants and lycopene in their composition and further disclose that the sources for lycopene and hydrophilic antioxidants comprising their composition are natural.

None of the prior art references cited *supra* clearly disclose cartilage extract/ cartilage extract components or pine bark extract as the components for their compositions.

Kosbab, however, discloses compositions comprising cartilage (bovine and shark and thus showing fish cartilage) or glycosaminoglycan = chondroitin sulphate (Page 24, Line 6) and antioxidant containing plant extracts (See e.g., Page 8, Lines 3-4), wherein antioxidants are: carotenoid, flavonoids and Vitamin E (page 43, Lines 1-11). The sources for carotenoids in the said composition are β -carotene, lutein, lycopene, zeaxanthin (Page 24, Lines 24-25) and sources for flavonoids are: extracts of bilberry (i.e., *Vaccinium myrtillus*), *Ginkgo biloba*, grape seed and pine bark (Page 23, Lines 26-32 and Page 24, Lines 10 and 20-21), green tea (i.e., *Camelia sinensis*, See Page 8, Line 4). Said composition has an antioxidant effect (Page 43, Lines 8-9 and Page 44, Lines 10-14). Kosbab further teaches vitamin c (i.e., ascorbic acid), zinc,

One having ordinary skill in the art would have been motivated to modify Greenberg's composition (Column 2, Lines 63-67; Column 3, Lines 36-40) according to the beneficial teachings from Bombardelli et al., because Bombardelli et al., remedy the deficiency in Greenberg's teachings of distinguishing between components comprising hydrophilic and liopphilic antioxidants and indicate the natural sources (plant species and extracts from those plant species) for those antioxidants (Page 6, Lines 47-53 and Page 7, Lines 1-4). Kosbab's beneficial teachings (Page 8, Line 4; Page 23, Lines 26-32; Page 24, Lines 6, 10, 20-21 and 24-25; page 43, Lines 1-11 and Page 44, Lines 10-14) remedy the deficiency in Greenberg's and Bombardelli et al's teaching by beneficially teaching that cartilage and chondroitin sulphate as components of Kosbab's composition, and further that the composition is also comprised of antioxidants obtained from a variety of natural sources (e.g., plants) and that glycosaminoglycan is one of the extractable compound from cartilage.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Greenberg's composition by incorporating beneficial teachings from Bombardelli et al., and

Kosbab, because each one of the cited prior art references teach a composition comprising hydrophilic and lipophilic antioxidants, wherein the sources for those antioxidants are natural (i.e., plant extracts) and Kosbab further teaches that said composition is comprised of antioxidants and cartilage extract/components (e.g., glycosaminoglycan) present in cartilage extract.

The concentration of individual antioxidant components or of components obtained from cartilage/cartilage extract in the aforementioned prior art references is either not disclosed or is not the same as in the claimed invention. However, the adjustment of particular conventional working conditions (e.g., concentrations of individual components comprising a given composition or ratios among different components of a composition) is deemed merely a matter of judicious selection and routine optimization of a result oriented parameter, which is well within the purview of the skilled artisan.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

14. Claims 65-85 and 88-91 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Greenberg (U.S. Patent 5,569,458) in view of Spraycar (, M. (editor). Stedman's Medical Dictionary. 1995. Williams and Wilkins, Baltimore, Page 121, Column 1, Lines 44-48), Bombardelli et al. (EP 0,6559,402) and Kosbab (WO 00/07607) and further in view of Hersh (U.S. Patent 5,906,811) and Murad (U.S. Patent 6,630,163).

Also claimed is a composition comprising *Acerola* extract, silicon dioxide, microcrystalline cellulose and inulin.

Teachings from Greenberg et al et al., Spraycar, Bobardelli et al (EP 06559,402) and Kosbab (WO 00/07607) are relied upon for the reasons set forth above. None of those references teach a composition comprising hydrophilic antioxidants named above, acerola extract, microcrystalline cellulose and inulin.

Hersh teaches a composition comprising proanthocyanadin from pine bark, or grape seed, *Acerola* (Column 19, Lines 3-8), zinc, ascorbic acid, vitamins C and E (Column 18, Lines 20-49). Hersh does not teach microcrystalline cellulose, inulin or silicon in his composition. Murad teaches compositions comprising vitamin E, proanthocyanadins from grape seed, Vitamin C, carotenoids (Column 14, Lines 25-32), microcrystalline cellulose, silica (i.e., silicon dioxide) (Column 32, Lines 19-25) and beneficial effects of inulin in a composition comprising inulin and grape seed (Column 5, Lines 19-25).

An artisan of ordinary skill would be motivated to combine the teachings from each one of the cited references because each one of the cited prior art references teach a composition comprising antioxidants in mixture with plant extracts, silicon, microcrystalline cellulose and inulin. Herse remedies the deficiency of Acerola extract in the composition of Greenberg et al., while Murad remedies the deficiencies of inulin, microcrystalline cellulose and silicon dioxide in teachings Greenberg et al.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Greenberg et al. according to the teachings from Bombardelli et al., Kosbab, Hersh and Murad because each one of the cited prior art references teach a composition comprising hydrophilic and lipophilic antioxidants, wherein the sources for those antioxidants are natural (i.e., plant extracts). While Kosbab further teaches that said composition is comprised of antioxidants and cartilage extract/ components (e.g., glycosaminoglycan) present in cartilage extract, Hersh et al., remedy the deficiency of Acerola extract and Murad remedies the deficiency of inulin, microcrystalline, zinc and silicon dioxide in the composition of Greenberg et al..

None of the above discussed prior art references teach the exact concentrations/ratios of each of the components/ chemicals as claimed in the instant invention. However, the adjustment of particular conventional working conditions (e.g., concentrations of individual components comprising a given composition or ratios among different components of a composition) is deemed merely a matter of judicious selection and routine optimization of a result oriented parameter, which is well within the purview of the skilled artisan.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. In response to rejections to Claims 65-85 under 35 U.S.C. §103(a) in Office Action mailed on 06/16/2003, applicants argue the same reasoning as discussed for Claim Rejections Under 35 U.S.C. § 102 (b) *supra* and further argues that applicant's instantly claimed invention is not obvious over examiner cited prior art references because Greenberg's composition is intended to resolve a different condition than that of enhancing collagen synthesis that applicant claims in the instantly claimed invention and that a skilled artisan attempting to develop a treatment for a skin condition would not be benefited with Greenberg's teachings. Applicant also argues that Bombardelli et al. reference does not teach advantage of combining lycopene, lipophilic and hydrophilic antioxidants in their composition for skin conditions. In

summary, applicant's arguments are around the fact that Greenberg's composition does not teach lycopene as a component in said composition and that combined teachings from Greenberg, Bombardelli et al. and Kosbab are not applicable for a skin condition.

Applicant's argument regarding deficiencies in Greenberg's composition or compositions that Greenberg, Bombardelli et al. and Kosbab teach have been fully considered but are not persuasive for the reasons that have been provided to settle applicant's arguments with regards to rejections under 35 U.S.C. § 102 (b) and in view of the grounds of rejections discussed *supra*.

In response to applicant's arguments that teachings from examiner cited prior art references do not disclose that their compositions would enhance collagen synthesis or resolve a skin condition and are therefore, not obvious over applicant's instantly claimed invention, the functional intended use of a composition does not materially change a given composition and is accordingly, not given any patentable weight. However, since teachings from examiner cited prior art references disclose a composition comprised of same/similar ingredients as recited in applicant's instantly claimed invention, said invention is obvious over the Examiner cited prior art references. Applicant should also note that the scope of claimed invention merely encompasses a composition comprising cartilage extract, hydrophilic antioxidants and limonene, not the application of said composition.


CONCLUSION

16. No Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571) 272-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(571) 272-0923

May 3, 2004



CHRISTOPHER R. TATE
PRIMARY EXAMINER